78. (New) The particle of Claim 1, wherein said particle comprises exactly six extremities.

REMARKS

Applicants thank Examiners Pellegrino and Prebilic for the time spent on this case and for the personal interview of October 24, 2002.

I. Issues under 35 U.S.C. §101 and §112, first paragraph

Claims 21 and 22 are rejected under 35 U.S.C. §101 because they allegedly are not supported by either a specific asserted utility or a well-established utility. They were also rejected under 35 U.S.C. §112, first paragraph, for allegedly being unable to show a skilled artisan how to make and use the invention. Applicants assert the language of the claims was not unclear as to the subject matter it was claiming, but herein amend the claims, and in light of these amendments, respectfully request withdrawal of the rejection.

II. Issues under 35 U.S.C. §112, second paragraph

Claims 17-19, 23-25 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicants amend the claims herein without prejudice and without acquiescence and, in light of these amendments, respectfully request withdrawal of the rejection.

III. Issues under 35 U.S.C. §102

Claims 1-4, 10, 14, 20, 21-22, 26, and 64-65 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ersek *et al.* (U.S. Patent No. 5,258,028) ("Ersek"). Applicants respectfully disagree. Applicants amend claim 1 herein without prejudice and without acquiescence to further the prosecution of this case, and support for these amendments is found in, for example, Figure 1. Furthermore, the new independent claims added herein are novel with respect to this art: Ersek fails to teach particles having bilateral symmetry (claim 73); particles having axes of any two adjacent arms at right angles from one another (claim 74); particles having extremities of the same shape and size (claim 75); particles wherein the

interstitial spaces of one particle will accept only one extremity of an adjacent particle (claim 76); and particles wherein the angles between adjacent extremities are approximately equal (claim 77).

A claim is anticipated only if each and every element as set forth in the claims is found in the reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, Applicants assert that Ersek does not anticipate claim 1 and its dependent claims because it does not teach the element of "**no more than six** tapered extremities..." (emphasis added). Thus, Applicants respectfully request removal of this rejection against Claim 1 and its dependents.

Claim 26 was rejected by the Examiner. Applicants assert Ersek does not teach an array of particles, nor does it teach that the particles are interlocked with one another, as claim 26 of the present invention describes. The text does not state that the particles are present in an array and, furthermore, does not state that the particles are interlocked with one another, as claim 26 of the present invention describes. Again, a claim is only anticipated if all elements are taught, and therefore Applicants respectfully request removal of this rejection.

IV. Issues under 35 U.S.C. §103

Claims 1-4, 9, 10, 26, 64 and 66 are rejected under 35 U.S.C. §103 as allegedly being unpatentable over Sheppard *et al.* (WO 94/08912) ("Sheppard"). Applicants respectfully disagree.

Applicants respectfully assert that the cited claims are not obvious in light of Sheppard. By the Examiner's own admission in the Office Action mailed August 27, 2002 on Page 4, Sheppard fails to contain or suggest all of the elements of the pending claims. To establish a *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981,180 USPQ 580 (CCPA 1974). In light of this criteria, Applicants assert that the Office has not established a *prima facie* case of obviousness to reject the claims under 35 U.S.C. §103. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991).

Furthermore, Applicants assert that Sheppard teaches away from the present invention. As acknowledged by the Examiner, Sheppard does not disclose a circular transverse cross-section configuration. In fact, Sheppard teaches away from the circular transverse configuration by teaching the square cross-section configuration. That is, Sheppard compares the advantages of a square cross-section over a circular cross-section, which would certainly steer another of skill in the art away from the circular cross-section, establishing it is not an obvious matter of design choice as the Examiner contends. On Page 12, L33-34, Sheppard states: "...(3) Plane-based coordination opportunities for aggregate that are an improvement on the point-to-point based coordination of spherical and random shapes..."

In addition to teaching away from the circular cross-section of Applicants' invention, the nature of Sheppard is a clear departure from the present invention, which would lead a skilled artisan in the field in a dissimilar direction. Applicants respectfully direct the Examiner's attention to the accompanying Declaration Under 37 C.F.R. §1.132 of Dr. Ed Margerrison.

Sheppard adumbrates on Page 12, Lines 13-19 that there may be embodiments where the aggregates are not packed into a "zero matrix", but the majority of Sheppard does, in fact, teach that the design of the arms in Figures 5 and 6 is to increase the strength by nesting tightly and providing 0% void volume. Furthermore, the essence of the entire reference teaches that the purpose of the aggregate or array of particles as per Figures 5 and 6 is to increase the strength of a composite material with the array being surrounded by a matrix material. Applicants strongly assert that Sheppard **as a whole** teaches away from the claims of the invention. Applicants respectfully remind the Examiner that a prior art reference must be considered in its entirety, *i.e.*, as a whole, ***including portions that would lead away*** from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Sheppard teaches that the composite is likely to have an increased strength and fracture toughness compared with other means of reinforcing composite structures. The array as shown in Figures 5 and 6 has essentially no open porosity within the structure, owing to the extremely highly reticulated structure that the "StarJack" shape gives. That is, it is mentioned that the arrangement described in Sheppard can often be achieved by mixing a

number of those granules and applying vibration through *e.g.* mechanical or ultrasound means. With minimal vibrational forces, the particles of Sheppard regularly pack, and the circular cross-section of the particles of the present invention would not allow this. In fact, the advantage of the circular cross-section of the present invention is to reduce the potential for forming this reticulated structure so that a number of the individual granules together will retain an open interconnected porosity. The shape of the Sheppard granules described in the vast majority of the reference would, therefore, teach away from the configuration of the present invention.

For example, on Page 7, Line 1 Sheppard states, "One aspect of the present invention is an aggregate having a unique three-dimensional shape theoretically capable of packing to 100% density without any void volume....." The particles of the present invention cannot pack to 100% density, nor would such density be desirable for treating a bone deficiency (an element of Claim 1).

Also, on Page 12, Line 2 it states, "As shown by Figs. 4-6, this property permits the aggregates to be arranged in a nesting configuration, wherein faces of one aggregate are disposed adjacent faces of neighboring aggregates in a regular array.

Applicants expand the above citation of the following passage on Page 12 from Sheppard:

> "We believe the Starjack, Tetratwin and Tetrastar represent novel classes of aggregate shapes with reticulate geometries marked by, for example:
>
> (1) The ability of same-class components of equivalent volume to ***nest*** uniformly;
>
> (2) Improved architectural properties of the nesting pattern itself (reticulate matrix), which may be varied in its thickness dimension in accordance with application demands;
>
> (3) Plane-based coordination opportunities for aggregate that are an improvement on the point-to-point-based coordination of spherical and random shapes or the line-to-line based coordination of fibrous reinforcements;
>
> (4) Substantially increased potential for crack path tortuosity.... (emphasis added)"

As described in the accompanying affidavit, Applicants assert that one skilled in the art would not recognize that the array of particles of the present invention illustrated in Figure 2 in the instant specification are in a "nested" array. Instead, one skilled in the art interprets the term "nested" to mean "to pack compactly together," and in the context of the teachings of Sheppard for flat surfaces of the arms in a "plane-based coordination", the packing would be so compact as to teach away from the bone deficiency-treating configuration of the array as taught by the Applicants.

Thus, Applicants assert that for multiple reasons Sheppard teaches away from the present invention, indicating that the pending claims are, in fact, not obvious.

* * * * * * * * *

Claims 5, 6, 9, 11-13, and 22 are rejected under 35 U.S.C. §103 as allegedly being unpatentable over Ersek in view of Chen *et al.* (U.S. Patent No. 6,180,606) ("Chen"); claims 15 and 16 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ersek in view of Kondo *et al.* (JP 171546); claims 7, 8, 18, 19, and 24 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ersek in view of Kelly (U.S. Patent No. 5,676,745); and claim 25 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ersek. Applicants respectfully disagree with all rejections.

Applicants respectfully assert that the cited claims are not obvious in light of Ersek alone or in combination with these references. As Applicants state *supra*, Ersek alone or combined does not contain or suggest all of the elements of Claim 1 as amended herein, and thus its dependent claims. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981,180 USPQ 580 (CCPA 1974). In light of this criteria, Applicants assert that the Office has not established a *prima facie* case of obviousness to reject the claims under 35 U.S.C. § 103. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991). Therefore, all of the 35 U.S.C. § 103 rejections over Ersek are improper, and Applicants respectfully request that the rejections be removed.

Ersek teaches using a number of these granules as exemplified in Figures 5 and 6 as an injectable material when used with a suitable carrier. Nowhere is disclosed an array of granules. The patent teaches that the function of the irregularities is to prevent dislodgement

of the granules following tissue ingrowth. It does not teach that an interlocking of granules can allow for both migration resistance and tissue ingrowth. Ersek teaches migration resistance dependent on injection in solution and allowing fibroblasts to anchor the particles into place (see, for example, Col. 3, L39-41; Col 2, L27-31; Col. 4, L12-27). In the present invention, the granules themselves prevent migration by interlocking in an array, which is reflected in claim 1. Ersek teaches away by teaching encapsulation of each particle. As presented in the interview and as stated in claim 1 ("particle will accept...one extremity of an adjacent...particle to facilitate interlocking...in an array"), the particle of the present invention "for use in a treating a bone deficiency" would function poorly if encapsulated, particularly by fibroblasts.

Applicants also strongly assert that Ersek **as a whole** teaches away from the claims of the invention. Applicants respectfully remind the Examiner that a prior art reference must be considered in its entirety, *i.e.*, as a whole, ***including portions that would lead away*** from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Applicants also submit that the rejections under 35 U.S.C. §103(a) for Sheppard, Ersek, and the combinations with Ersek are each an application of an "obvious to try" standard in the field of shaped bone particles. For Sheppard, the reference teaches a square cross-sectional configuration and the advantages therewith, and although Applicants strongly assert this teaches away from the present invention, Applicants also suggest the Examiner is improperly citing an obviousness rejection wherein the rejection is more accurately an "obvious to try" rejection. The "obvious to try" standard has been held to constitute an improper ground for a 35 U.S.C. § 103 rejection. *In re O'Farrell*, 858, F.2d 894, 903 (Fed. Cir. 1988). An "obvious-to-try" situation exists when a general disclosure may pique an inventor's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result or indicate that the claimed result would be obtained if certain directions were pursued. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990). Similarly, Ersek does not teach Applicants invention, and although the Examiner alleges the particles in Ersek are obvious, Applicants assert the encapsulated particles teach away from the present invention and the rejection is in fact an "obvious to try" rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P01952US0 from which the undersigned is authorized to draw.

Dated: 11/27/02

Respectfully submitted,

By _____

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Version to Show Markings

1. (Once Amended) A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion; and

[at least four] no more than six tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles, wherein said array of shaped particles provides for treating a bone deficiency.

21. The [bone deficiency] particle of Claim 20 wherein said bone deficiency is selected from the group consisting of a fracture, break, loss of bone, weak bone, brittle bone, hole in bone, void in bone, disease of bone and degeneration of bone.

22. The [disease] particle of Claim 21 wherein said disease is selected from the group consisting of osteoporosis, Paget's disease, fibrous dysplasia, osteodystrophia, periodontal disease, osteopenia, osteopetrosis, primary hyperparathyroidism, hypophosphatasia, fibrous dysplasia, osteogenesis imperfecta, myeloma bone disease and bone malignancy.

Pending claims as of October 2002

1. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion; and

no more than six tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles, wherein said array of shaped particles provides for treating a bone deficiency.

2. The particle of Claim 1 wherein at least three of said extremities lie in a plane.

3. The particle of Claim 1 wherein said particle has six extremities.

4. The particle of Claim 1 wherein said particle is comprised of a material selected from the group consisting of ceramic, bioactive glass, polymer, polymer/ceramic composite, and polymer/glass composite.

5. The particle of Claim 4 wherein said ceramic is comprised of a calcium salt.

6. The particle of Claim 5 wherein said calcium salt is selected from the group consisting of calcium sulfate, calcium carbonate, calcium phosphate and calcium tartarate.

7. The particle of Claim 6 wherein said particle is comprised of calcium sulfate.

8. The particle of Claim 7 wherein said calcium sulfate is in the form of gypsum.

9. The particle of Claim 4 wherein said particle is comprised of bioactive glass.

10. The particle of Claim 4 wherein said particle is comprised of a polymer.

11. The particle of Claim 10 wherein said polymer is selected from the group consisting of polypropylene, polylactic acid, polyglycolic acid and polycaprolactone.

12. The particle of Claim 4 wherein said particle is comprised of a polymer/ceramic composite.

13. The particle of Claim 4 wherein said particle is comprised of a polymer/glass composite.

14. The particle of Claim 1 wherein said particle has a diameter of about 3-10 millimeters.

15. The particle of Claim 1 wherein said particle has a diameter of about 4-8 millimeters.

16. The particle of Claim 1 wherein said particle has a diameter of about 6 millimeters.

20. The particle of Claim 1 wherein said treatment of a bone deficiency is selected from the group consisting of augmentation of bone, repair of bone, replacement of bone, improvement of bone, strengthening of bone and healing of bone.

21. The particle of Claim 20 wherein said bone deficiency is selected from the group consisting of a fracture, break, loss of bone, weak bone, brittle bone, hole in bone, void in bone, disease of bone and degeneration of bone.

22. The particle of Claim 21 wherein said disease is selected from the group consisting of osteoporosis, Paget's disease, fibrous dysplasia, osteodystrophia, periodontal disease, osteopenia, osteopetrosis, primary hyperparathyroidism, hypophosphatasia, fibrous dysplasia, osteogenesis imperfecta, myeloma bone disease and bone malignancy.

26. An array of shaped particles wherein said array comprises a plurality of shaped particles, said shaped particles comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles, wherein said array of shaped particles provides for treating a bone deficiency.

64. The particle of Claim 1, wherein the particle is ceramic.

65. The particle of Claim 1, wherein said particle is comprised of a resorbable material.

67. The array of Claim 26 wherein said plurality of shaped particles comprises a mixture of particles comprised of different materials.

68. The array of Claim 67 wherein said different materials are selected from the group consisting of ceramic, calcium salt, bioactive glass, polymer, polymer/ceramic composite, and polymer/glass composite.

69. The array of Claim 26 wherein said interstitial spaces of one said particle will accept only one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles, wherein said array of shaped particles provides for treating a bone deficiency.

70. The array of Claim 70 wherein said interlocking of adjacent particles in said array provides adequate porosity to allow ingrowth from a host bone.

71. The array of Claim 70 wherein said porosity is between about 40% and about 80%.

72. The array of Claim 26 wherein said porosity is between about 60% and about 80%.

73. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles, wherein the particle has bilateral symmetry in at least one plane of said particle.

74. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles, wherein the axes of any two adjacent arms are at right angles from one another.

75. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles, wherein the extremities are of the same shape and size.

76. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept only one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles.

77. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein the angles between any adjacent extremities in the particle are approximately equal.

78. The particle of Claim 1, wherein said particle comprises exactly six extremities.